DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 13, 2015

Domain Surgical Incorporated
Mr. Curtis Jensen
Vice President of Quality and Regulatory Affairs
1370 South 2100 East
Salt Lake City, Utah 84108

Re: K142229
Trade/Device Name: Laparoscopic FMsealer
Regulation Number: 21 CFR 878.4400
Regulatory Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 22, 2014
Received: December 24, 2014

Dear Mr. Jensen:

This letter corrects our substantially equivalent letter of January 2, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Laparoscopic FMsealer

Indications for Use:

The Laparoscopic FMsealer is an electrosurgical instrument intended for use in open and laparoscopic surgical procedures, including general and gynecologic procedures where ligation and division of vessels, including lymph vessels, is desired. It can be used to ligate and divide vessels up to and including 7 mm and bundles as large as will fit in the jaws of the instrument.

The Laparoscopic FMsealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these purposes.

Prescription Use ___X_____ AND/OR Over-The-Counter Use: _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

SUBMITTER

Domain Surgical, Inc.
1370 South 2100 East
Salt Lake City, Utah 84108
Phone: 801-924-4958
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Contact Person: Curtis Jensen
Date Prepared: May 16, 2013

DEVICE

Name of Device: Laparoscopic FMsealer
Common or Usual Name: Electrosurgical cutting and coagulation device and accessories
Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR §878.4400)
Regulatory Class: II
Product Code: GEI

PREDICATE DEVICES

LigaSure Vessel Sealing System (Product Code GEI) 510(k) #K043273
Open FMsealer (Product Code GEI) 510(k) #K141484

No reference devices were used in this submission.

DEVICE DESCRIPTION

Electrosurgical cutting and coagulation devices (and accessories) are devices intended to remove tissue and control bleeding by use of high-frequency electrical current (see 21 CFR §878.4400). They are classified as Class II (510(k)) devices.

The Laparoscopic FMsealer is a sterile, single-patient use, hand-held surgical instrument intended for ligation and division of vessels. The Laparoscopic FMsealer must be connected to a generator (Domain Surgical's FMwand Generator) by an accessory cable (Domain Surgical's FMwand Power Module). It is capable of blunt dissection, grasping and division of tissue enclosed within its jaws during open or laparoscopic procedures. The outer diameter of the instrument shaft is 5mm, with a working length of 36cm.

The Laparoscopic FMsealer includes a rotation knob, front lever and two actuation buttons. The rotation knob, located at the distal end of the handle, allows for a full 360 degrees of rotation of the jaws to improve visibility of the tissue as well as permit access to tissues on differing planes. The front lever closes the jaws of the device which allows pressure to be applied to the tissue between the jaws. The actuation buttons activate the transfer of current from the generator to the tip of the device which creates the heat necessary for sealing and dividing.

This system creates sealing, cutting and coagulation by the application of heat and compression (from the opposing jaws of the device) to tissue bundles and vessels interposed between the jaws of the instrument.

The Laparoscopic FMsealer has been shown to cut and seal vessels (veins and arteries) up to and including 7mm in diameter.

INDICATIONS FOR USE

The Laparoscopic FMsealer is an electrosurgical instrument intended for use in open and laparoscopic surgical procedures, including general and gynecologic procedures where ligation and division of vessels, including lymph vessels, is desired. It can be used to ligate and divide vessels up to and including 7mm and bundles as large as will fit in the jaws of the instrument.

The Laparoscopic FMsealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these purposes.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICEs

The Laparoscopic FMsealer employs ferromagnetic induction to generate heat at the tip. This method of heat generation is the same as for the Open FMsealer (K141484), and differs from the LigaSure System which uses the resistance of the target tissue and electrical current to produce the heat necessary for cutting and sealing (bipolar electrosurgery).

Device Comparison Table

Performance Feature	Laparoscopic FMsealer	Open FMsealer (K141484)	LigaSure Vessel Sealing System (K043273)
Manufacturer	Domain Surgical, Inc.	Domain Surgical, Inc.	ValleyLab
510(k) Number	To be assigned	K141484	K043273
Prescription/OTC	Prescription Only	Prescription Only	Prescription Only
Product Code	GEI	GEI	GEI
Classification Regulation	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Basis Intended Use	Sealing, cutting and coagulation of soft tissue	Sealing, cutting and coagulation of soft tissue	Sealing, cutting and coagulation of soft tissue
Heat Generation Method	Ferromagnetic induction provides an elevated temperature surface which will cauterize soft tissue as it seals and cuts.	Ferromagnetic induction provides an elevated temperature surface which will cauterize soft tissue as it seals and cuts.	Application of bipolar electrosurgical energy to tissue interposed between the jaws of the instrument.
Shaft Diameter	5mm	N/A – The Open FMsealer for open procedures only.	5mm
Operational Control Method	Controlled power delivered to tip of connected accessory	Controlled power delivered to tip of connected accessory	Controlled power delivered to tip of connected accessory
Mode of Operation	Intermittent Operation	Intermittent Operation	Intermittent Operation
Output Type	Type CF	Type CF	Unknown
Bench Testing	The Laparoscopic FMsealer passed all bench tests performed. Details are found in this submission.	The FMwand System (Handpiece) passed all bench tests performed. Details are found in the original 510(k) submission #K141484.	Unknown
Meets applicable sections of IEC 60601-2-2	Yes. Details are found this submission.	Yes. Details are found in 510(k) #K141484.	Unknown
Biocompatibility Testing	Materials used in the patient-contacting portions of the Laparoscopic FMsealer are either known to be biocompatible or have passed testing performed according to ISO 10993-5 (Cytotoxicity), 10993-10 (Acute Systemic Toxicity) and 10993-11(Sensitization and Irritation).	Materials used in the patient-contacting portions of the Open FMsealer are either known to be biocompatible or have passed testing performed according to ISO 10993-5 (Cytotoxicity), 10993-10 (Acute Systemic Toxicity) and 10993-11(Sensitization and Irritation). Details are found in the original 510(k) submission, K141484.	Unknown
Sterilization Method	Laparoscopic FMsealer is for single-patient use and will be provided sterile. Sterilization method will be Ethylene Oxide: SAL 10^{-6}.	Open FMsealer is for single-patient use and provided sterile. Sterilization method is Ethylene Oxide: SAL 10^{-6}.	Unknown

The differences between the Laparoscopic FMsealer and the predicate devices are discussed and analyzed in detail in the appropriate section of this submission. None of the differences raise new questions of safety and effectiveness.

PERFORMANCE DATA

Questions of safety and effectiveness are the same for this device as they are for the predicate devices and other similar devices on the market. All applicable bench testing was performed with the Laparoscopic FMsealer to assure that it functions as intended. Testing included:

Vessel Sealing Tool Thermal Test

Ex-Vivo Vessel Sealing Test Results (2mm-7mm Porcine Arteries)

In-vivo GLP Acute Animal Study – Laparoscopic Stress Testing

In-vivo GLP Chronic Animal Study – Vessel Sealing

Questions of safety and effectiveness are the same for this device as they are for the predicate devices and other similar devices on the market. Electrical safety testing was successfully performed on this device according to IEC 60601-1 and IEC 60601-2-2.

The patient-contacting materials used in the Laparoscopic FMsealer were chosen for their biocompatibility, function and suitability for the intended use of this device. The materials have been tested to assure that they comply with the ISO 10993 standards and 510(k) Memorandum G95-1.

CONCLUSIONS

The Laparoscopic FMsealer is substantially equivalent to the predicate devices. The intended use of the Laparoscopic FMsealer is the same as the predicate devices with the addition of use in laparoscopic procedures. This minor difference has no effect on safety or effectiveness. The Laparoscopic FMsealer differs from the LigaSure device in technological characteristics; however the differences do not raise different types of questions of safety and effectiveness. The information presented in this 510(k), including the bench and animal testing, demonstrates that the Laparoscopic FMsealer is as safe and effective as the predicate devices for its intended use.